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10/822,580	04/12/2004	Scott A. Entenman	AUGA07000021	2643

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EXAMINER
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SHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

ED

<b>Office Action Summary</b>	<b>Application No.</b> 10/822,580	<b>Applicant(s)</b> ENTENMAN ET AL.	
	<b>Examiner</b> Laura C. Schell	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-33 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7-10, 13-17, 19, 20, 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Jusiak et al. (US Patent No. 6,901,216). Jusiak discloses a fluid warming cassette (Fig. 1) comprising: a first sheet (Fig. 2, 32) and a second sheet (34), made from polyethylene, joined together to form a fluid container with a periphery, the periphery having a proximal end, a distal end and first and second sides there between; a fluid channel (Fig. 1, 21) in the fluid container between the first sheet and the second sheet; first and second rails (30a and 30b) disposed between the first sheet and the second sheet, inside the periphery, near the first and second sides, respectively; and a planar stiffener (Fig. 5i discloses that portions 202 are extensions of planar stiffener 20. Col. 4, lines 37-41 disclose that tongue portion 20 is made of stiffer material that can be sandwiched between the two sheets, while col. 5, lines 32-38 disclose that portions 202 are made from the same material as 20, and that they extend from each rail), separate from the first and second rails (Figs. 1 and Fig. 5 disclose that the planar stiffeners are

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separate from the rods, also shown in Fig. 5j), disposed between the first sheet and the second sheet (col. 4, lines 37-41), and extending from the first to the second rail (as Fig. 5i discloses, portions 202 are positioned such that they each extend down sides of the rails, and because portions 202 are the same material and are extensions of 20, they clearly extend from the first to the second rail. The examiner would like to point out that applicant has not used claim language stating that the planar stiffener must extend between the rails, just from one rail to the other, and the claim language does not disclose which side of each rail the stiffener must extend from), near the proximal end (Figs. 1 and 5i disclose that the planar stiffener is located at the proximal end, i.e. the end that is handled by the user when inserting the cassette).

In reference to claim 2, Jusiak further discloses that each of the first and second rails has a multi-lateral cross-section (col. 3, lines 59-60).

In reference to claim 3, Jusiak further discloses that each of the first and second rails has a first surface supporting a respective arch of the first sheet (if the rails are circular rods, as shown in Fig. 1, then the sheet formed over the rod would be arched because of the rod, and the rod would support this arch) and a second surface, opposite the first surface and flush with the second sheet (they sheets would be flush with each other where they meet and bond).

In reference to claim 4, Jusiak discloses that the stiffener has a first elongated portion extending between the first and second rails (fig. 9 discloses that the stiffener 20 extends between the first and second rails) and a second portion protruding from the

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first portion in the direction of the distal end (Fig. 9 further discloses that they extend towards the distal end).

In reference to claim 5, Jusiak further discloses that the serpentine fluid channel (21) is disposed between the first and second rails (30a and 30b) and between the second portion and the distal end (fig. 9, for example).

In reference to claim 7, Jusiak further discloses that the stiffener forms a handle portion (portion 20 is used as a handle col. 4, lines 12-14) in the proximal end constituted of the first and second sheets sandwiching the stiffener (col. 4, lines 37-41 disclose that the stiffener is sandwiched between the two sheets).

In reference to claim 8, Jusiak discloses that the stiffener has a first elongated portion extending between the first and second rails and a second portion protruding from the first portion toward the fluid channel (fig. 9).

In reference to claim 9, Jusiak discloses that the handle portion includes a label surface (20).

In reference to claim 10, Jusiak also discloses first (24) and second (26) ports in fluid communication with the fluid channel (21).

In reference to claims 13-17 and 19, Jusiak further discloses that the rails can be made of any conventional material, such as plastic or metal (col. 3, lines 63-65). Jusiak also discloses that the stiffener can be made of any polymeric material or metal (col. 4, lines 31-36).

In reference to claim 20, Jusiak further discloses that the first and second sheets are made from polyethylene (col. 5, lines 54-55).

In reference to claim 27, Jusiak further discloses that the fluid channel has a serpentine pattern (Fig. 1).

Claims 29-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Jusiak (US Patent No. 6,901,216). Jusiak discloses a fluid warming cassette (Fig. 1) comprising: a flexible fluid container (10) with two edges and two ends; a fluid channel (21) in the fluid container; first and second rails (30a and 30b) disposed in the fluid container, near first and second edges of the fluid container, respectively; and a handle portion (20; col. 4, lines 12-14) formed near a proximal end of the fluid container by sandwiching a planar piece in the fluid container (col. 4, lines 37-41).

In reference to claim 30, Jusiak discloses that the planar piece is for stiffening the fluid container transversely between the first and second rails (Figs. 1 and 5i).

In reference to claim 31, Jusiak discloses that at least one rail has a shape for keying the insertion of the cassette into a fluid warming unit (col. 3, lines 59-61).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11, 12, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jusiak in view of Tousignant et al. (US Patent No. 5,205,348). Jusiak discloses the device substantially as claimed including ports (40 and 38), however, Jusiak does not disclose expressly that the ports are disposed perpendicularly to the fluid container or that they constitute insertion stops. Tousignant discloses two ports (Figs. 4-6) that are perpendicular to the fluid container. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Jusiak with the perpendicular ports as taught by Tousignant in order to provide ports that the sheets/films can seal around, rather than sealing to the ports individually as taught by Jusiak; by sealing around the ports, as taught by Tousignant, the ports come up perpendicularly through the sheet and there is no risk of the sealing engagement coming undone by the ports sliding out of position (col. 6, line 63 through col. 7, line 18).

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jusiak et al. (US Patent No. 6,901,216) in view of Tousignant et al. (US Patent No. 5,205,348). Jusiak discloses the device substantially as claimed including a fluid warming cassette

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(Fig. 1) comprising: a flexible, planar fluid container (10) with a periphery, two edges, a proximal end (near 20), and a distal end (near 12); a fluid channel (21) in the fluid container, the fluid channel having two ends (ends at 24 and 26); first and second rails (30a and 30b) disposed in the fluid container, inside the periphery, near the first and second edges, respectively; at least one of the rails for keying the fluid warming cassette for insertion into a fluid warming unit (col. 3, lines 59-61), a planar stiffener (Fig. 5i discloses that portions 202 are extensions of planar stiffener 20. Col. 4, lines 37-41 disclose that tongue portion 20 is made of stiffer material that can be sandwiched between the two sheets, while col. 5, lines 32-38 disclose that portions 202 are made from the same material as 20, and that they extend from each rail), separate from the first and second rails (Figs. 1 and Fig. 5 disclose that the planar stiffeners are separate from the rods, also shown in Fig. 5j), extending from the first to the second rail (as Fig. 5i discloses, portions 202 are positioned such that they each extend down sides of the rails, and because portions 202 are the same material and are extensions of 20, they clearly extend from the first to the second rail. The examiner would like to point out that applicant has not used claim language stating that the planar stiffener must extend between the rails, just from one rail to the other, and the claim language does not disclose which side of each rail the stiffener must extend from), near the proximal end (Figs. 1 and 5i disclose that the planar stiffener is located at the proximal end, i.e. the end that is handled by the user when inserting the cassette); and two fluid ports (40 and 38), each fluid port in fluid communication with a respective end of the fluid channel (ports 40 and 38 are in communication with channel ends 26 and 24, respectively, as



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seen in Fig. 1). Jusiak does not disclose expressly that the ports are disposed perpendicularly to the fluid container or that they constitute insertion stops. Tousignant discloses two ports (Figs. 4-6) that are perpendicular to the fluid container. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Jusiak with the perpendicular ports as taught by Tousignant in order to provide ports that the sheets/films can seal around, rather than sealing to the ports individually as taught by Jusiak; by sealing around the ports, as taught by Tousignant, the ports come up perpendicularly through the sheet and there is no risk of the sealing engagement coming undone by the ports sliding out of position (col. 6, line 63 through col. 7, line 18).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jusiak in view of Bakke (US Patent No. 6,608,968). Jusiak discloses the device substantially as claimed except for the stiffener being made of cardboard or cardstock. Bakke, however, discloses a fluid-warming envelope (Fig. 4, 16) with a paperboard stiffener (26) to aid in inserting the envelope into the warmer. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Jusiak with the paperboard stiffener as taught by Bakke, in order to provide another inexpensive material for use as a stiffener with the cassette.

Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jusiak in view of Greenblatt (US Patent No. 4,707,587). Jusiak discloses the device

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substantially as claimed except for each sheet being made of a plurality of layers.

Greenblatt, however, discloses a fluid warming jacket (Figs. 7 and 8, 7) in which each of the first and second sheets is made of a plurality of layers. Each sheet is made of an inner layer of plastic and an outer layer of aluminum, which are laminated together (col. 2, line 66 through col. 3, line 4). Thus, the inner layer (plastic) has a lower melting point than the outer layer (aluminum). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Jusiak with the laminated layers of Greenblatt in order to provide a jacket with a conductive layer and a non-reactive layer that contacts the blood.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jusiak in view of Tousignant and further in view of Kujawski et al. (US Patent No. 4,568,330) and further in view of Lundquist (US Patent No. 4,227,525). Jusiak in view of Tousignant discloses the kit substantially as claimed including: a fluid warming cassette with fluid channel, rails, planar stiffener, and inlet and outlet ports perpendicular to the warming cassette. Jusiak in view of Tousignant, however, does not disclose expressly inlet and outlet lines, a drip chamber or a bubble trap. Kujawski discloses a fluid chilling chamber (Fig. 1, 54) which has an inlet line (52) including an inlet end (44) for receiving fluid from sources, a drip chamber (42) with an inlet coupled to the first end and an outlet coupled to the inlet port (where 52 connects to 54); and an outlet line (56) including a bubble trap (144 and 146) with an inlet coupled to the outlet port (where 54 connects to 56) and an outlet (64), and an outlet end (72) for delivering warmed fluid. Kujawski, however,

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does not disclose an injection site. Lundquist discloses an infusion set with an injection site. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Jusiak in view of Tousignant with the inlet and outlet lines, drip chamber and bubble trap as taught by Kujawski and the injection site as taught by Lundquist, in order to provide a kit that is ready for use with a patient and infusion source.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-5, 7-33 and 35 have been considered but are moot in view of the new ground(s) of rejection.

Upon further review of the claims, the examiner determined that previously applied Jusiak still anticipates the claims. The new rejection of the claims under Jusiak and other secondary references is applied above.

Therefore the allowability of claims 1-5, 7-33 and 35 is withdrawn.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LCS

*LCS*

KEVIN C. SIMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Simons*